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No. 05-1455

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U.S. PATENT & TRADEMARK OFFICE

In the

United States Court of Appeals
for the Federal Circuit

IN RE RONALD A. SCHACHAR,

Appellant.

APPEAL FROM THE UNITED STATE PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES
APPLICATION SERIAL NO. 09/589,626

BRIEF OF APPELLANT SCHACHAR

William A. Munck
Daniel E. Venglarik
DAVIS MUNCK, P.C.
900 Three Galleria Tower
13155 Noel Road
Dallas, Texas 75240
(972) 628-3600
Attorney for Appellant

mead

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE SCHACHAR _____ v. _____

No. 05-1455

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

RONALD A. SCHACHAR certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

RONALD A. SCHACHAR

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

REFOCUS GROUP INC.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

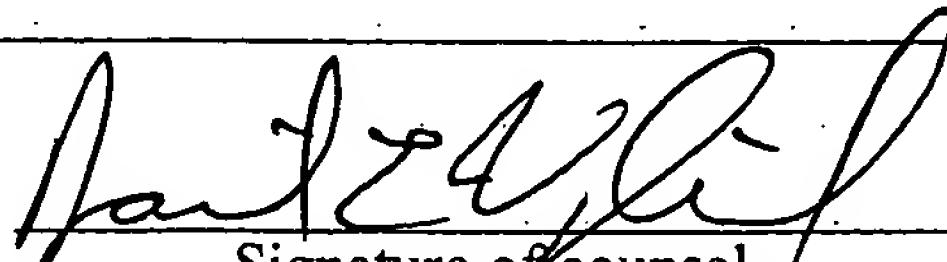
4. There is no such corporation as listed in paragraph 3.

5. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

William A. Munck, Daniel E. Venglarik, DAVIS MUNCK, P.C. (f/k/a NOVAKOV, DAVIS & MUNCK P.C., f/k/a NOVAKOV DAVIS P.C.)

September 6, 2005

Date



Signature of counsel

Daniel E. Venglarik
Printed name of counsel

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STATEMENT OF RELATED CASES

No appeal in or from the same application or any related application currently pending in United States Patent and Trademark Office has been before this or any other court. No case pending in this or any other court will directly affect or be directly affected by this Court's decision in the pending appeal.

JURISDICTIONAL STATEMENT

The United States Court of Appeals for the Federal Circuit has jurisdiction over this appeal under 35 U.S.C. § 141.

STATEMENT OF ISSUES

The sole issue in this appeal is whether the United States Patent and Trademark Office erred in holding that claims 1–7 and 12–17 (“the Rejected Claims”) in Appellant’s subject patent application serial no. 09/589,626 are anticipated under 35 U.S.C. § 102(b) by Appellant’s prior U.S. Patent No. 5,354,331 (“the ‘331 patent”).

Specifically, the issue on appeal turns on: (1) whether the United States Patent and Trademark Office Board of Patent Appeals and Interferences (“BPAI”) erred as a matter of law in concluding that the Rejected Claims may be interpreted as reading on an intermediate structure that does not “contact[] the sclera” or “expand[] said contacted sclera,” rather than only a completed prosthesis ready for implantation into an eye, (2) whether the BPAI’s conclusion that the body of the completed expansion

band within the '331 patent has "first and second ends" is supported by substantial evidence, and (3) whether the BPAI's conclusion that the planform (shape) of the expansion band within the '331 patent causes expansion of the contacted sclera is supported by substantial evidence.

STATEMENT OF THE CASE

This is an appeal from a decision by the BPAI affirming the prior rejection of claims 1–7 and 12–17 pending within patent application serial no. 09/589,626 as being anticipated by the '331 patent. See ADD6–ADD8¹; A5–A7.² Claims 1–24 are pending in the application. The utility rejection under 35 U.S.C. § 101 of claims 1–7 and 12–17 as being directed to non-statutory subject matter was reversed by the BPAI. ADD4; A3. The utility and prior art rejections of pending claims 8–11 and 18–21 were reversed by the BPAI. ADD4, ADD8; A3, A7. Pending claims 22–24 had previously been allowed. A51. Appellant is appealing only the portion of the BPAI decision affirming rejection of claims 1–7 and 12–17 as anticipated under 35 U.S.C. § 102(b) by the '331 patent. A copy of all pending claims may be found at Appendix pages A70–A72.

STATEMENT OF RELEVANT FACTS

¹ Addendum pages, in the reference convention followed throughout this brief.

² Appendix pages, in the reference convention followed throughout this brief.

The subject patent application filed June 7, 2000 claims priority as a continuation-in-part to application serial no. 08/946,975 filed October 8, 1997 through co-pending application 09/061,168 filed April 16, 1998 and through co-pending application serial no. 09/472,535 filed December 27, 1999. A18. The '331 patent issued October 11, 1994, more than one year prior to the earliest priority date claimed in the subject patent application. A105.

Pending independent claim 1 in Appellant's subject patent application, representative of the Rejected Claims, reads:

1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

A70. The claimed invention is directed, in general, to a prosthesis intended for implantation into a human eye. A19, A25. To focus on objects at different distances, the human eye changes the focal length of the biconvex crystalline lens therein (referred to as "accommodation") by action of the ciliary muscles connected by zonules to the elastic capsule of the lens, altering the curvature of the lens:

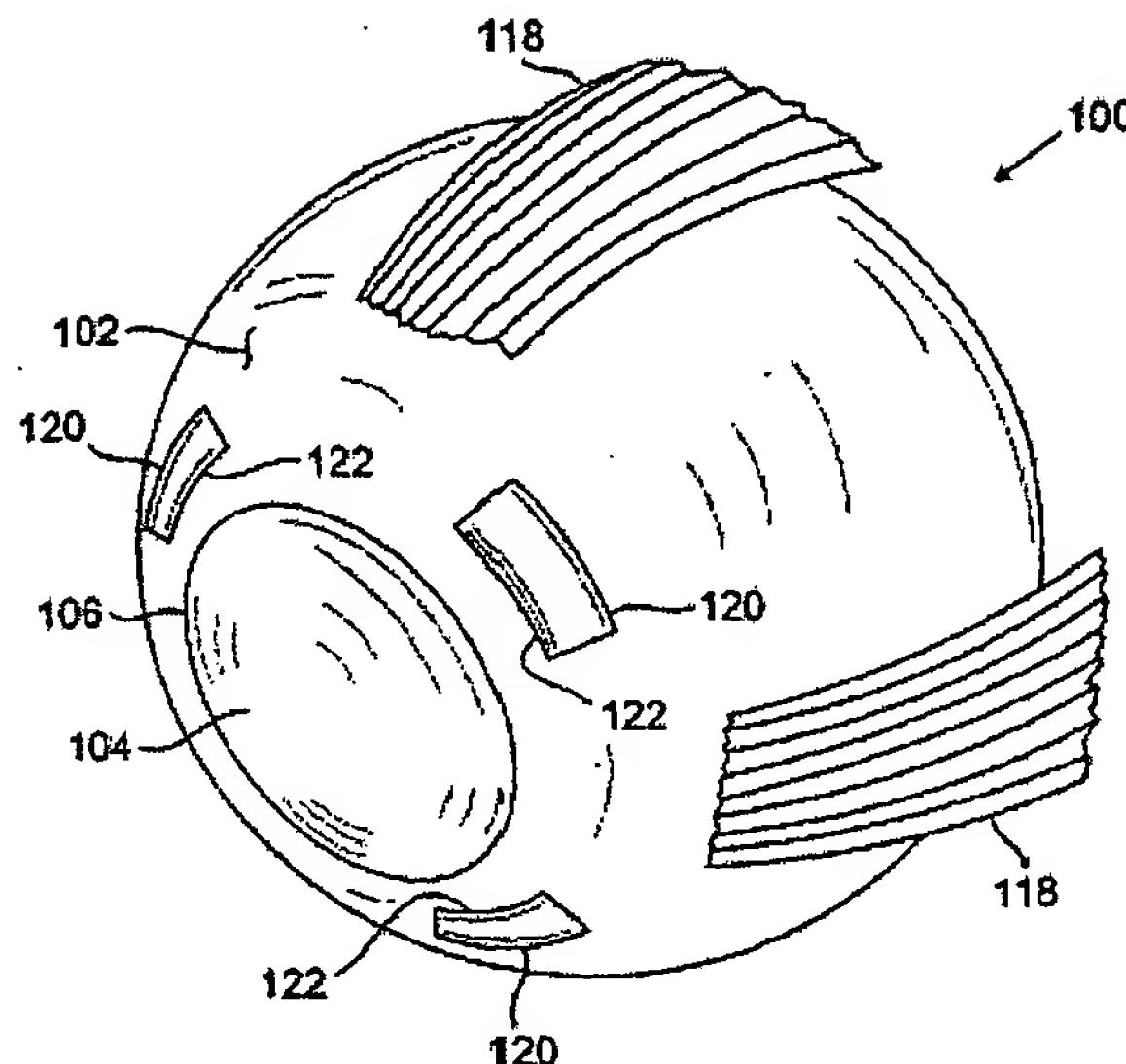


FIG. 1

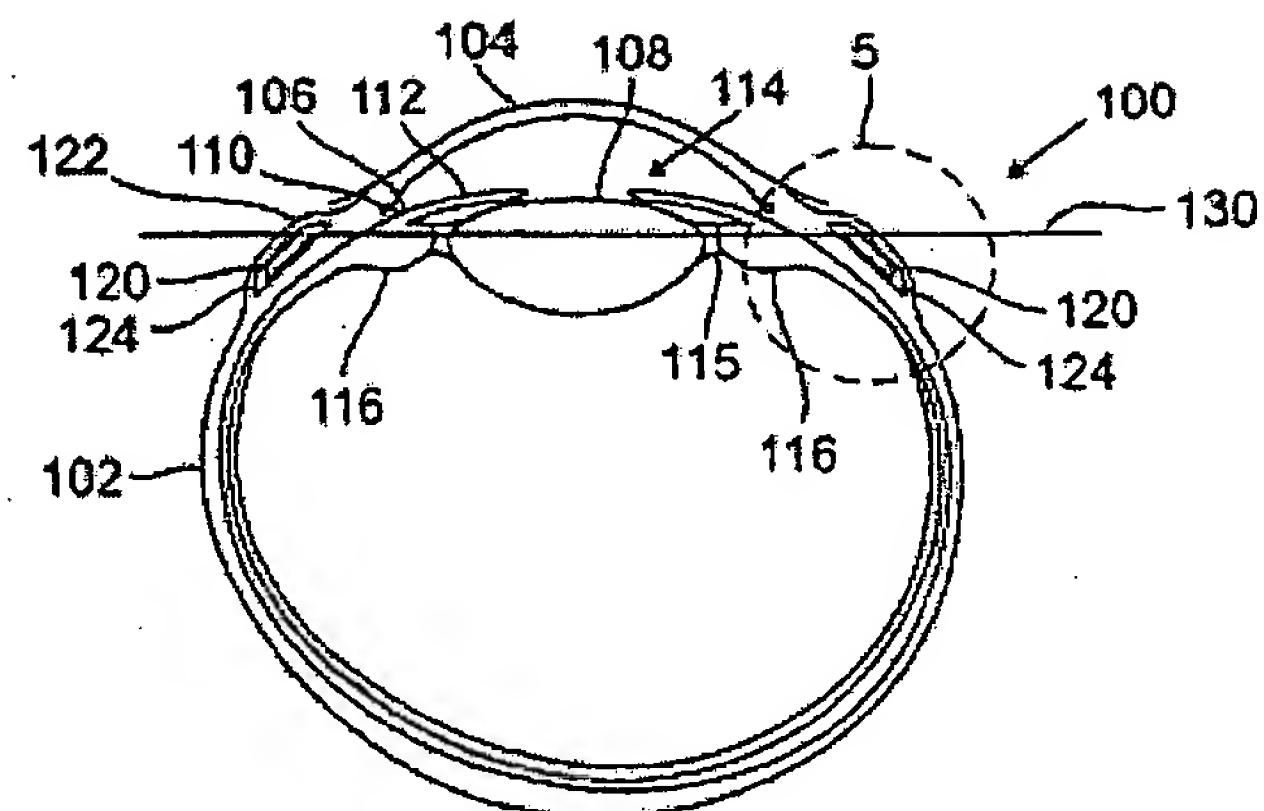


FIG. 4

A20–A22, A119, A122.³ The lens 108 is suspended by the zonules from the equator 110 or periphery of the lens to the ciliary muscle 116 attached to an inner surface of the sclera 102. A130, col. 4, ll. 42–47.

The ability to focus on near objects is often gradually lost in individuals over 40 years of age, a condition referred to as “presbyopia” and typically corrected by “reading” glasses (or bifocals). A22. Under the classic Helmholtz theory of how the human eye functions, this condition results from loss of elasticity of the lens capsule and/or sclerosis of the lens, and cannot be surgically corrected. A22–A23.

³ Appellant's subject patent application serial no. 09/589,626 claims priority to, and incorporates by reference, the prior patent application corresponding to the patent included in the appendix from which Figures 1 and 4 above were copied: serial no. 08/946,975 (U.S. Patent No. 6,007,578). A18–A19.

Dr. Schachar, the named inventor in Appellant's subject patent application, developed a different theory regarding how the human eye functions: contraction of the ciliary muscle increases tension on the zonules, causing a decrease in the peripheral volume of the lens and an increase in the lens's equatorial diameter, changing the focal length of the lens. A111, col. 3, l. 54 – col. 4, l. 1. Under Dr. Schachar's theory, presbyopia arises because the lens continues to grow throughout the life of the human, while the sclera, to which the ciliary muscle is attached, does not. A111, col. 4, ll. 15–25. As a result of the increasing lens diameter over time, the effective working distance of the ciliary muscle – that is, the distance across which the ciliary muscle can pull the peripheral edge of the lens – decreases, resulting in loss of ability to focus on near objects. A111, col. 4, ll. 26–41. Presbyopia, Dr. Schachar discovered, can be surgically treated by increasing the effective working distance of the ciliary muscle. A111, col. 4, ll. 42–46.

The '331 patent, also naming Dr. Schachar as the inventor thereof and cited as the basis for rejecting the Rejected Claims, suggests one approach to increasing the effective working distance of the ciliary muscle by expanding the sclera, using a frustoconical continuous ring or "band" 102:

FIG. 1

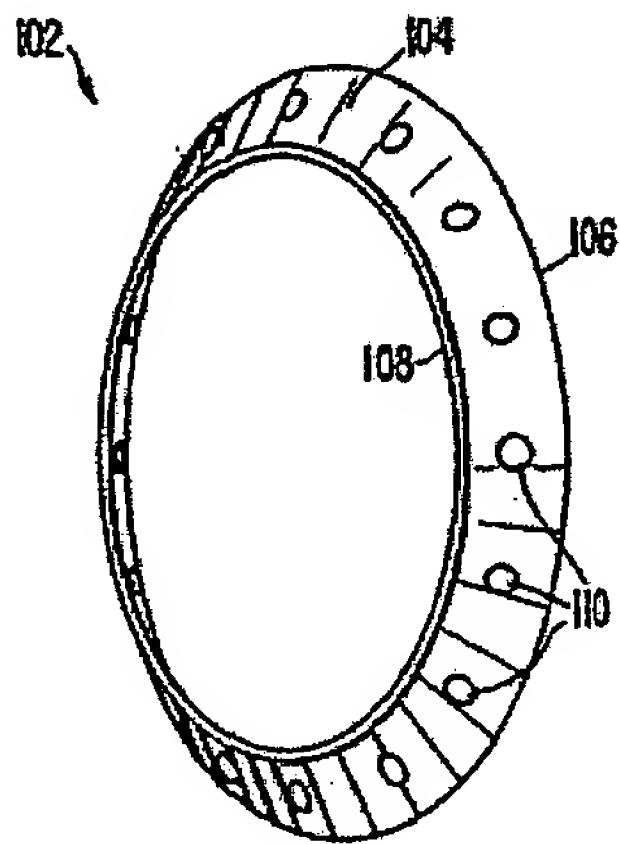
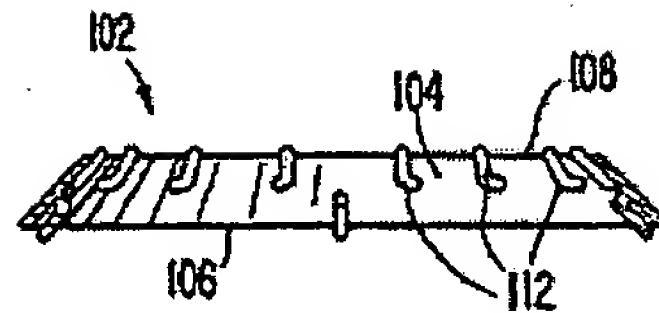


FIG. 7

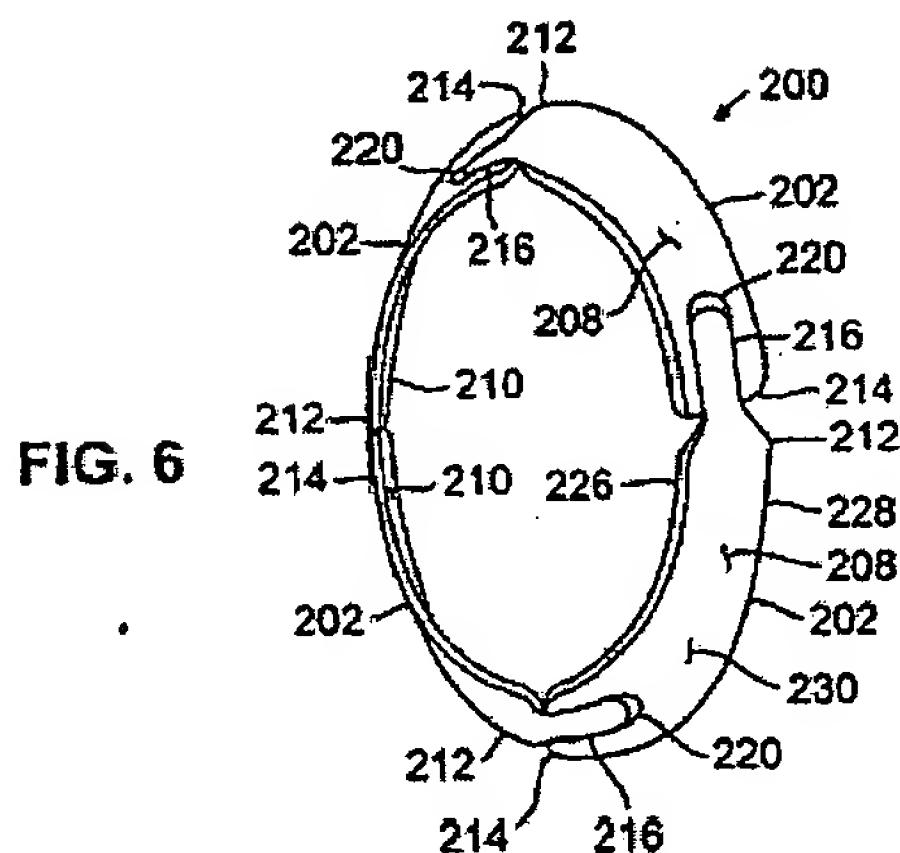


A106. The band 102 is fastened to the outer surface of the sclera of the eye (by, for instance, sutures 112 over the anterior rim 108 and through suture holes 110) and exerts a radially outward tension on portions of the sclera to which the ciliary muscle is attached – that is, lifting or “pulling up” on the sclera by the sutures. A112, col. 5, ll. 5–50, col. 6, ll. 1–11. A portion of the ‘331 patent reads:

The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band. The band may be adjustable in circumference. For example the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band. The length of the overlap may be adjusted, for example, by means of a tangential screw mechanism to adjust the circumference of the band and thereby the amount by which the sclera is expanded.

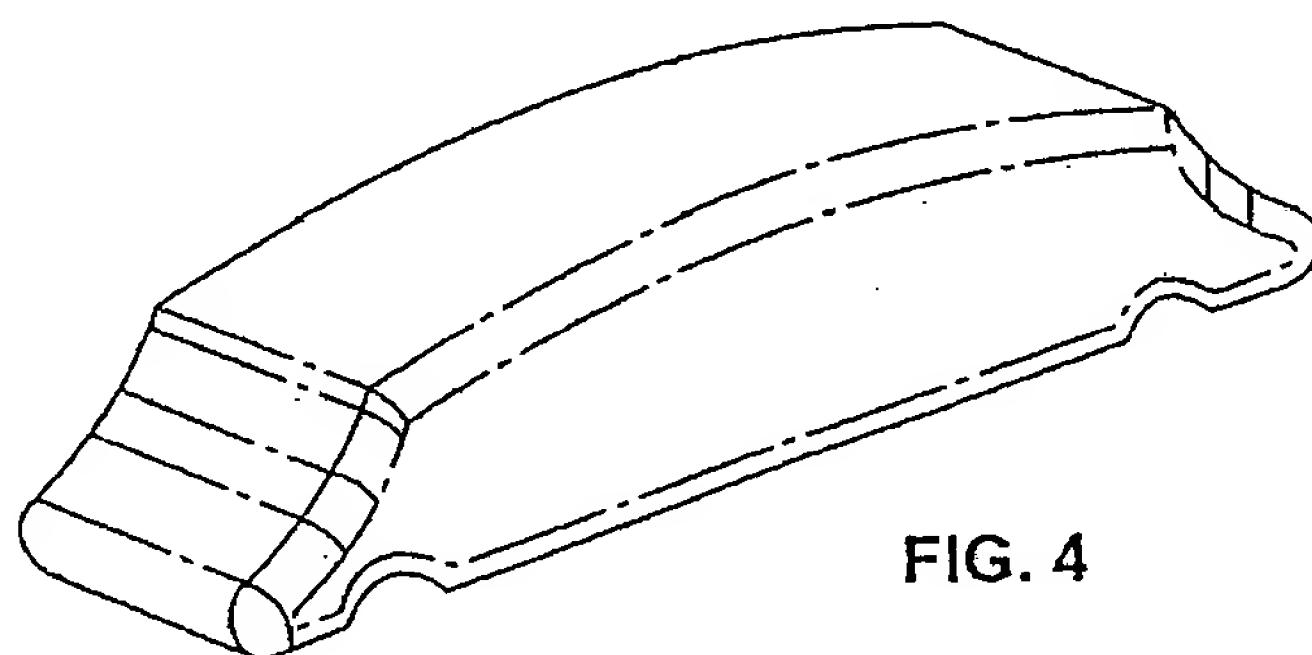
A13, col. 7, ll. 1–12. Neither of these alternative embodiments (to a unitary stamped or molded band) is depicted or further described in the ‘331 patent, although a later patent issuing on a continuation-in-part to the ‘331 patent depicts and describes a

segmented band that "comprises a plurality of parts or bodies, each of which has first and second ends":



A139; compare A51, ll. 14-17.

Dr. Schachar's subject patent application relates to a different approach to expanding the sclera: implanting a prosthesis within a surgically formed pocket or tunnel within the sclera. A25, ll. 2-12. The prosthesis includes a body with an elongate planform and a relatively thick profile:



A30, l. 14 - A35, l. 17, A46. As with the use of prior prosthesis designs invented by Dr. Schachar for this approach to correcting presbyopia, pockets or tunnels 120 are

surgically formed through and beneath the sclera 102 at several locations around the lens, in the region of the ciliary muscle 116:

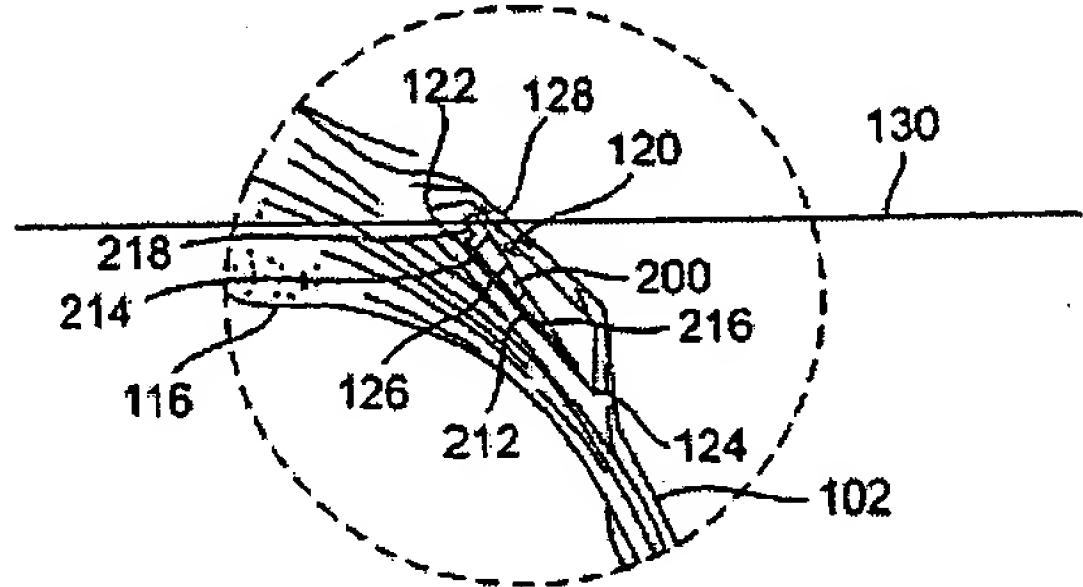


FIG. 5

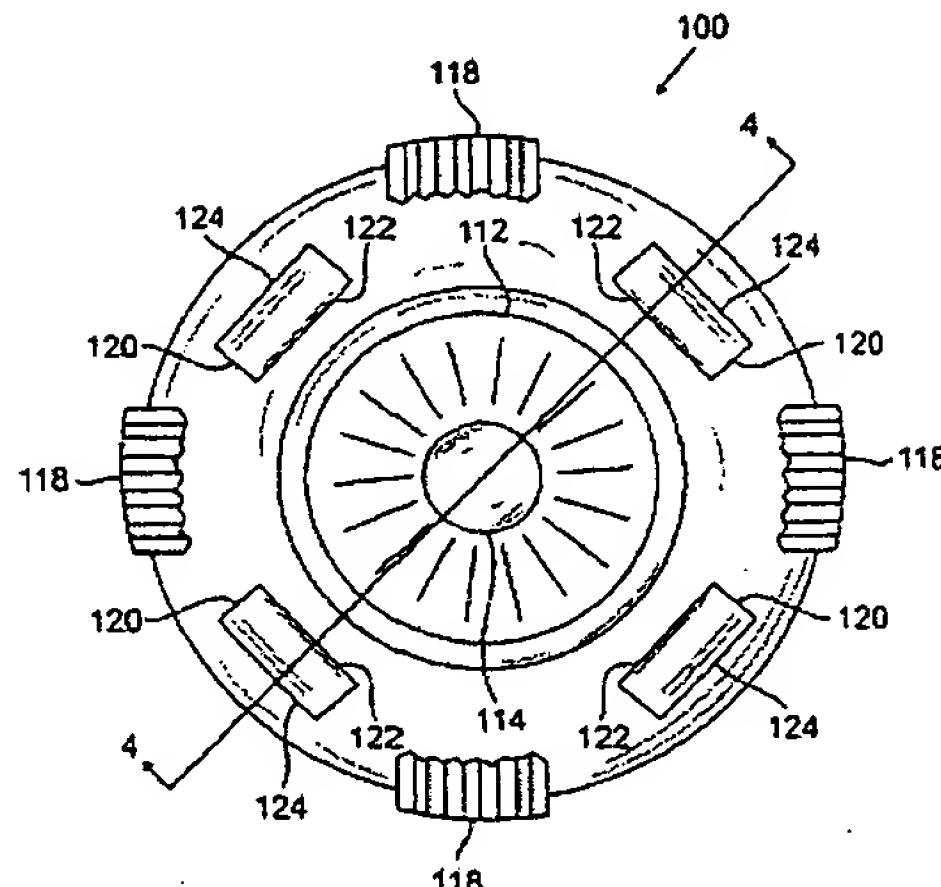


FIG. 2

A29, 1. 8 – A30, 1. 2, A120, A122, A164. The prosthesis, when implanted, exerts an outward force on the sclera contacting the upper surface of the prosthesis, elevating the overlying “belt loop” portion of the sclera with respect to the globe of the eye (and surrounding scleral regions) to increase the effective working distance of the ciliary muscle and restoring accommodation. A29, ll. 14–19. However, an implanted prosthesis has a tendency to slide or rotate within the surgically formed pocket. A30, ll. 3–13. While prior prosthesis designs were thin and flat (or wedge-shaped), see A123–A128, better results can be obtained by thicker implants:

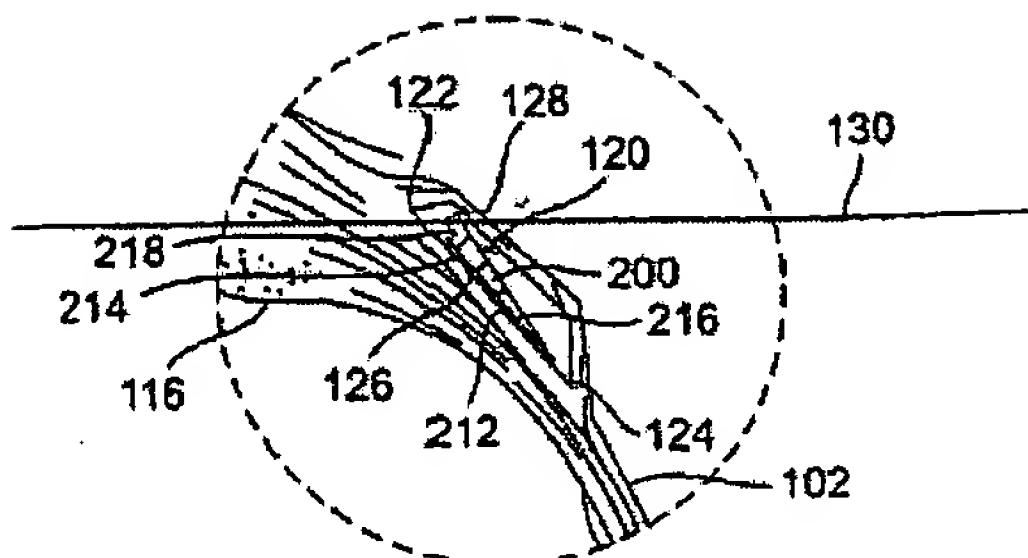


FIG. 5

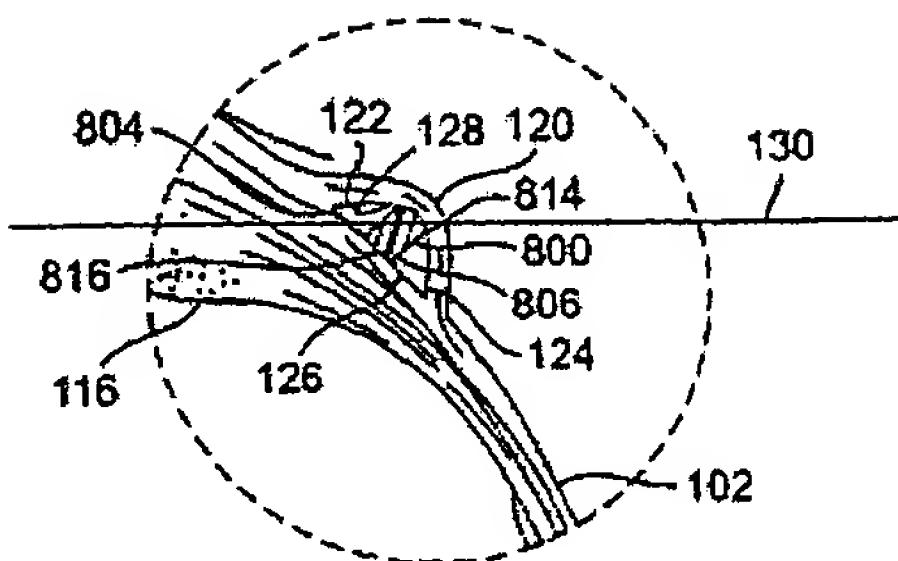


FIG. 30

A151, A160.⁴ Since thicker prostheses have more of a tendency to topple or rotate beneath the “belt loop,” means for stabilizing the prosthesis are provided, such as either (a) suturing, in a prior design (A159, A166, ll. 65–67), or (b) curved surfaces with specific curvatures relative to the curvature of the globe of the eye, together with grooves near the ends of the prosthesis that extend outside the pocket or tunnel and rest on adjacent scleral regions (A32, l. 20 – A36, l. 21).

The Rejected Claims currently stand rejected only for asserted anticipation of those claims by the '331 patent.

SUMMARY OF ARGUMENT

The independent claim representative of the Rejected Claims recites that the prosthesis “contacts the sclera” and “expands said contacted sclera.” These

⁴ Appellant's subject patent application serial no. 09/589,626 claims priority to, and incorporates by reference, the prior patent application corresponding to the patent included in the appendix from which Figures 5 and 30 above were copied: serial no. 09/061,168 (U.S. Patent No. 6,280,468). A18–A19.

limitations require the claim to be read only on a completed prosthesis, ready for implantation, not on the raw material for a prosthesis or an intermediate structure.

The cited alternative embodiment within the '331 patent, in which the expansion band is formed from a strip of material curved around on itself with overlapping ends that may slide relative to one another in order to adjust the circumference of the expansion band, is an intermediate structure not ready for engrafting onto an eye. Prior to surgical use, the ends of that intermediate structure must be fixed relative to each other to form a continuous ring or band capable of providing tensile support to sutures looped around a rim of the expansion band and lifting or pulling up on the sclera. While the ends of the strip of material could possibly be identified within the completed expansion band, fixing the ends of the strip of material relative to each other, necessary to form a functional expansion band, results in a "body" that is a continuous ring or band, and no longer has "first and second ends." Accordingly, none of the embodiments within the '331 patent includes a prosthesis body that "contacts the sclera" and "expands said contacted sclera," and has "first and second ends" as well.

The claim feature of the prosthesis body planform (shape) causing scleral expansion is not found in the '331 patent, where scleral expansion is caused by lifting or pulling by sutures or equivalent means. The claims feature of the planform

expanding the contacted sclera is not found in the '331 patent, where regions of the sclera nearby the contacted regions are expanded (lifted or pulled up) rather than the contacted regions themselves.

ARGUMENT

The sole issue presented in this appeal turns on (a) interpretation of rejected claims under appeal, which is a question of law reviewed *de novo* by this Court, and (b) conclusions regarding the applicability of subject matter described and enabled by the prior art to the claims, which are questions of fact reviewed by this Court for substantial evidentiary support. *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (en banc) (claim construction is a matter of law reviewed *de novo*); *Dickinson v. Zurko*, 527 U.S. 150, 165 (1999) (no exception to Administrative Procedure Act for review of Patent Office determinations); *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (substantial evidence standard is appropriate for review of BPAI factfindings); *In re Hyatt*, 211 F.3d 1367, 1371-72 (Fed. Cir. 2000) (anticipation is question of fact reviewed for substantial evidence).

I. The '331 Patent Does Not Disclose a Completed Expansion Band "Body" Having "First and Second Ends".

As noted above, the '331 patent suggests alternatives to a band of unitary construction, in which the band is formed from either multiple segments joined end-

to-end or a single strip of material curved around to overlap the ends:

The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band. The band may be adjustable in circumference. For example the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band. The length of the overlap may be adjusted, for example, by means of a tangential screw mechanism to adjust the circumference of the band and thereby the amount by which the sclera is expanded.

A13, col. 7, ll. 1-12. The above-quoted language also suggests that the band may be adjustable (in size), at least prior to engrafting onto the surface of the eye. *Id.*

As noted above, representative claim 1 reads:

1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

A70. The Examiner rejected claim 1 as anticipated by the '331 patent, reasoning that the alternative embodiments described by the above-quoted statements within the '331 patent satisfied all limitations of claim 1:

The Applicant's remarks have been reviewed. The Applicant states that '[t]here is no first end and there is no second end of the scleral expansion band described in the *Schachar* reference' (Paper No: 12, page 16, lines 7-8) and thus ignores the embodiment that is explicitly characterized as having ends (column 7, lines 6-8). Moreover, it must be pointed out that the transitional term 'comprising' is 'inclusive or open-ended and does not exclude additional unrecited elements' (MPEP 2111.03). Therefore, even though the scleral expansion band mentioned

at column 7, lines 1-3, for example, is ring-like in form, it comprises a plurality of parts or bodies, each of which has first and second ends, a planform, and other features set forth in present claim 1 and others.

A51, ll. 9-17. Upon review, the BPAI essentially adopted the first argument above, but remained silent regarding the second:

The subject limitation in the claim simply calls for the recited prosthesis to comprise ‘a body having a first end and a second end.’ Schachar’s adjustable prosthesis clearly comprises such a body in the form of a strip of material having first and second ends. These ends do not cease to exist even when the strip assumes its operative configuration. Hence, the Schachar scleral expansion band, without any modification or adjustment thereto, fully meets the terms of the claim including the recitation of a body having a first end and a second end.

ADD13-ADD14; A12-A13. It is unclear from the BPAI decisions whether the BPAI interpreted the recited element of a “body” within claim 1 as encompassing either or both of the raw material (a strip of material from which the prosthesis is formed) and/or an intermediate structure (the adjustable band prior to engrafting onto the eye), as well as the completed expansion band. *Id.*⁵ Accordingly, the interpretation of claim 1 will be addressed first, then the application of the ‘331 patent to the claim.

A. The Claim Term “Body” Does Not Encompass Raw Materials or Intervening Structures, Only the Completed Prosthesis Body.

Claims during examination (and on review from Patent Office determinations

⁵ See also A5.

during examination) are given their broadest reasonable interpretation consistent with the specification. *Hyatt*, 211 F.3d at 1372. It is noteworthy, however, that the broadest reasonable interpretation is adopted, not the broadest possible interpretation.

Claim 1 is directed to a prosthesis “that contacts the sclera of an eyeball” and includes a body “expand[ing] said contacted sclera.” As such, the “body” limitation requires a completed device that is ready for implantation, and cannot be read on either the raw material or the intermediate structure disclosed in the ‘331 patent. Both qualifiers (“contacts the sclera of an eyeball” and “expands said contacted sclera”) indicate that the claim is directed to a completed prosthesis, ready for implantation into a scleral pocket. For functional reasons described below, the expansion band of the ‘331 patent must be in completed form prior to contacting the sclera, and accordingly would not be in either the beginning (strip of material) or intermediate (adjustable band) form when “contact[ing] the sclera” and/or “expand[ing] said contacted sclera.”

As described above, the expansion band of the ‘331 patent operates by being engrafted onto the surface of an eye, over the sclera in the region of the ciliary muscle. Sutures (or other suitable means) through the sclera and passing over the outermost rim of the band lift or pull up on the sclera to expand the sclera and thereby increase the effective working distance of the attached ciliary muscle. To function,

the expansion band must therefore be essentially rigid, capable of supporting the tension associated with lifting or pulling up on the sclera by the sutures. As those skilled in the art (and most high school physics students) will recognize, an adjustable band formed from a strip of material with overlapping ends will not provide such tensile support, but would instead collapse, unless the overlapping ends were somehow fixed in position relative to each other (by bonding, etc.). As long as the ends of the band remain movable with respect to each other, tension on the rim of the band (from the sutures) will cause the ends to simply slip with respect to each other, and the band will simply collapse onto the surface of the sclera rather than exert a radially outward force on the sclera. The sutures do not simply hold the expansion band in place, but instead exert tension lifting up on the sclera. Without a uniformly rigid band, such tension would not be supported.

The '331 patent notes that the size of the globe of the eye in different people will vary, requiring bands of differing diameters. A112, col. 6, ll. 18-24. The adjustable expansion band alternative is thus proposed to avoid having to form unitary-construction bands of various sizes. However, those skilled in the art will recognize that the adjustable band is merely an intermediate structure, not suitable for engrafting onto the surface of an eye. At some point prior to engrafting the expansion band onto an eye, the ends of an adjustable band must be fixed relative to each other

in order to form a structure capable of providing tensile support to sutures lifting or pulling up on the sclera. Accordingly, the adjustable band in the '331 patent does not contact or expand the sclera; only the completed expansion band contacts and expands the sclera when properly engrafted to the eye.

For these reasons, the "body" recited in claim 1 of a prostheses that "contacts the sclera" and "expands said contacted sclera" can only be read on the completed expansion band from the '331 patent, with either unitary construction or having ends fixed relative to each other. The limitation "body" cannot be read on either a simple strip of material or an adjustable band with overlapping ends movable relative to each other.

B. The "Body" of the Completed Expansion Band in the '331 Patent Does Not Have "Ends".

The BPAI adopted the somewhat metaphysical view that the (overlapping) ends of an adjustable expansion band "do not cease to exist" when the band is placed into completed form (i.e., when the ends are fixed relative to each other). ADD13; A12. However, this confuses the completed expansion band with the strip of material from which the expansion band was formed. While the ends of the strip of material used in forming the expansion band may still be perceived, the "body" formed by fixing the overlapping ends relative to one another does NOT have ends, but is instead a

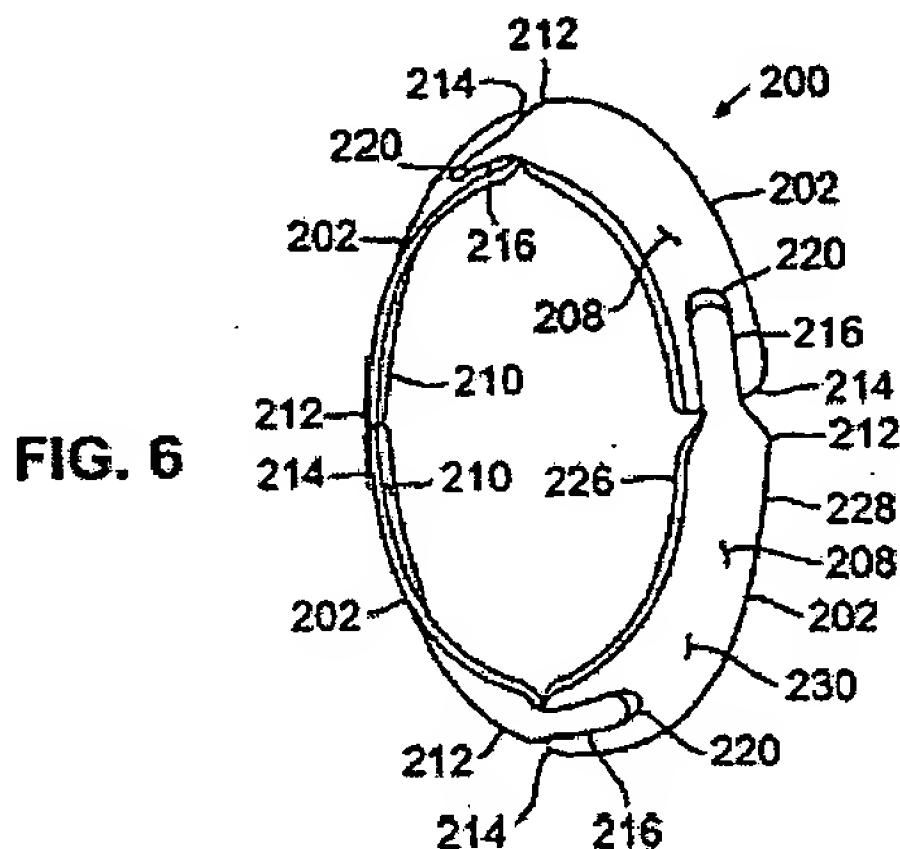
continuous band or ring.⁶ Regardless of whether formed by unitary construction or from a strip of material curved around with overlapping ends, physically the completed expansion band in the '331 patent must have the structure of a continuous band or ring in order to provide the tensile support necessary to achieve scleral expansion. Thus, while one might be able to identify the ends of a strip used to form the expansion band (e.g., from a region of increased thickness), the body – and in particular the planform – of the completed expansion band will NOT have ends, but will instead be a continuous ring or band.

As noted above, the Examiner cited both alternative embodiments from the '331 patent (the adjustable band formed by a strip with overlapping ends, and the band formed from a plurality of segments or parts joined end-to-end) as anticipating claim 1. The BPAI, however, did not rely on the segmented band alternative in affirming rejection of claim 1. ADD4–ADD7, ADD11–ADD14; A3–A6, A10–A13. Appellant respectfully suggests that by declining to rely on the segmented band alternative, the BPAI's decision may be viewed as a tacit concession that affixing the ends of two or more segments to each other can result in a continuous structure that

⁶ To the extent that some portion(s) of the overlapping ends may remain “loose” after the two ends of the strip of material are fixed relative to each other to form a continuous band, those strip portions do NOT form part of the prosthesis body, but are instead merely superfluous material that may (and most likely would) be removed prior to engrafting the expansion band onto an eye.

no longer has ends.

Whether tacitly conceded or not, however, the joinder of two ends of a structure to form a continuous "body" having no ends is apparent from considering the segmented expansion band alternative depicted in one of Dr. Schachar's prior patents:



A139. The individual segments 202 forming the expansion band 200 in the illustration above each have "first and second ends." However, the segments are joined by affixing one end of each segment to an end of another segment, to form a continuous band or ring. Therefore the resulting body of the expansion band formed by joining those segments end-to-end does NOT have any ends, but is instead continuous. While the component structure employed to form the expansion band has ends (but lacks the ability, by itself, to exert tension on the sutures passing through the sclera), the resulting expansion band does not. Similarly, affixing the ends of a

single strip of material relative to each other – whether in an overlapping or end-to-end configuration – results in an expansion band body without any ends: a continuous ring or band.

The completed expansion band in the '331 patent is the only structure disclosed therein that "contacts the sclera" and "expands said contacted sclera." However, the completed expansion band in the '331 patent is a continuous structure that does not include "first and second ends." No other structure is disclosed in the '331 patent that both "contacts the sclera" and "expands said contacted sclera" AND comprises a body having "first and second ends," as required by claim 1. Accordingly, the BPAI decisions affirming the rejection for anticipation by the '331 patent are not supported by substantial evidence.

C. A Claim of Similar Form Has Previously Been Allowed Over the '331 Patent.

Dr. Schachar's prior issued U.S. Patent No. 6,299,640 ("the '640 patent") includes an issued claim having similar form to rejected independent claim 1:

Subject application

1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

US 6,299,640

1. A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising an elongated base having a first end and a second end and means for expanding said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

A70, A185, col. 9, ll. 55–59. The '331 patent was of record during prosecution of the '640 patent. A170. Appellant respectfully suggests that the differences between the two claims are not so great that one claim should be held to be anticipated by the '331 patent when the other has not.

II. The Planform of the Expansion Band in the '331 Patent Does Not Expand the Contacted Sclera.

Independent claim 1 also recites that the prosthesis body has “a planform that expands said contacted sclera.” In Dr. Schachar’s prosthesis design for scleral implants, the shape (or planform) of the prosthesis body causes scleral expansion when implanted under the sclera within surgically formed pockets or tunnels. The width and thickness of the elongate body causes the sclera over the prosthetic implant to traverse a greater distance than the surrounding scleral regions, under which no prosthesis has been implanted.

The shape of the expansion band in the '331 patent, on the other hand, does

not, by itself, cause expansion of the sclera. Rather, the continuous ring shape of the expansion band provides tensile support for the sutures or equivalent means. In addition, the frustoconical shape (an annular cylinder or ring with angled sidewalls) allows one rim of the expansion band to rest on the sclera while sutures looped around the opposite rim and passing through the sclera pull up on the sclera, toward the outer rim of that angled sidewall. The lifting or pulling up by the sutures towards the outer rim of the expansion band “expands” (or causes expansion of) the sclera, not the shape of the expansion band.

In addition, the region of the sclera contacted by the expansion band is not expanded in the ‘331 patent. As noted, one rim of the expansion band contacts the sclera, while sutures through nearby portions of the sclera pull up on and expand those portions of the sclera. Thus, it is not “said contacted sclera” that is expanded by the expansion band of the ‘331 patent, but instead nearby regions around which the sutures pass.

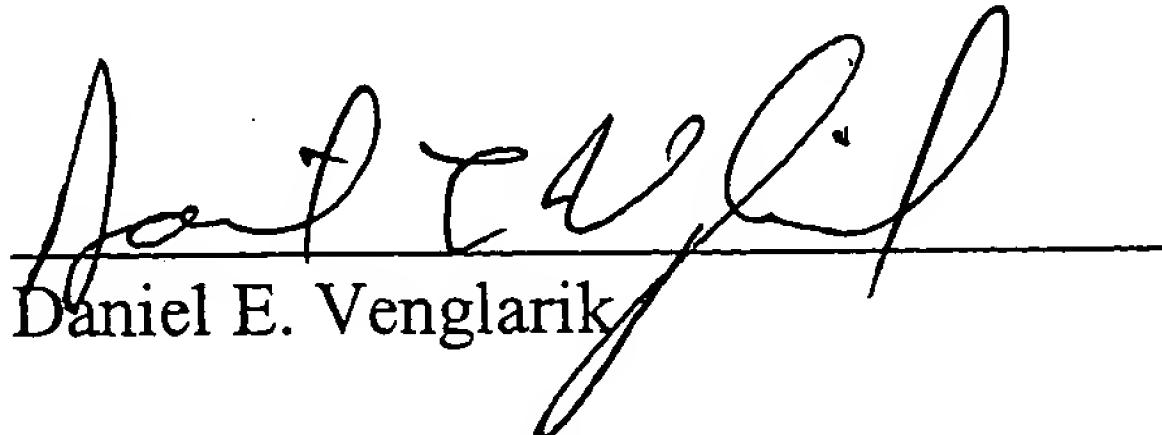
The planform or shape of the expansion band in the ‘331 patent does not expand the sclera, and the expansion band in the ‘331 patent does not expand the contacted regions of the sclera, as required by the limitations of claim 1. Accordingly, the BPAI decisions affirming the rejection for anticipation by the ‘331 patent are not supported by substantial evidence.

CONCLUSION

The Rejected Claims are not anticipated by the expansion band disclosed in the '331 patent. In its completed, functional form, ready for use in an eye, the body of expansion band disclosed in the '331 patent does not have "ends," but is instead a continuous band or ring. In addition, the "planform" or shape of the expansion band in the '331 patent does not "expand[]" the sclera, and the expansion band in the '331 patent does not expand the contacted sclera. Accordingly, Appellant requests that the rejection of claims 1-7 and 12-17, and the BPAI's decisions affirming that rejection, be reversed.

Respectfully submitted,

DAVIS MUNCK, P.C.



Daniel E. Venglarik

900 Three Galleria Tower
13155 Noel Road
Dallas, Texas 75240
(972) 628-3600 (main number)
(972) 628-3616 (fax)

ATTORNEYS FOR APPELLANT

ADDENDUM

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONALD A. SCHACHAR

Appeal No. 2005-0076
Application No. 09/589, 626

MAILED

NOV 23 2004

U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

Before COHEN, FRANKFORT, and MCQUADE, Administrative Patent Judges.

MCQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Ronald A. Schachar appeals from the final rejection of claims 1 through 21. Claims 22 through 24, the only other claims pending in the application, stand allowed.

THE INVENTION

The invention relates to a prosthetic device for treating presbyopia. Representative claim 1 reads as follows:

1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

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DAVIS MUNCK

-ADD2-

Appeal No. 2005-0076
Application No. 09/589,626

THE REJECTIONS

Claims 1 through 21 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1 through 7 and 12 through 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,354,331 to Schachar.

Claims 8 through 11 and 18 through 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schachar.

Attention is directed to the main and reply briefs (filed December 23, 2003 and May 13, 2004) and to the final rejection and answer (mailed August 14, 2003 and March 9, 2004) for the respective positions of the appellant and the examiner regarding the merits of these rejections.

DISCUSSION

I. The 35 U.S.C. § 101 rejection of claims 1 through 21 as being directed to non-statutory subject matter

The examiner, citing MPEP § 2105 and the 1987 Official Gazette Notice entitled "Animals-Patentability" (1077 O.G. 24),¹ considers claims 1 through 21 to be directed to non-statutory subject matter because they include within their scope a human being. By way of example, the examiner points to the language in

¹ A copy of the notice is appended to the answer.

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claim 1 reciting a prosthesis "that contacts the sclera of an eyeball."

The appellant agrees that a claim directed to or covering a human being would be non-statutory under § 101, but insists that claims 1 through 21 are directed to a prosthesis per se, not a prosthesis in combination with a human being or any part thereof.

A fair reading of claims 1 through 21 supports the appellant's construction. These claims define a prosthesis per se, and the language therein referring to the sclera and other parts of the human eye merely sets forth the environment in which the claimed prosthesis is intended to be used.

Accordingly, we shall not sustain the standing 35 U.S.C. § 101 rejection of claims 1 through 21 as being directed to non-statutory subject matter.

II. The 35 U.S.C. § 102(b) rejection of claims 1 through 7 and 12 through 17 as being anticipated by Schachar

The Schachar patent discloses a prosthetic scleral expansion band for treating presbyopia by increasing the effective working range of the ciliary muscle. Figures 1 through 5, Figures 6 and 7 and Figures 8 and 9 respectively illustrate different embodiments of the expansion band. Each embodies a one-piece circular structure. Schachar teaches, however, that

[t]he scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band. The band may be adjustable in circumference. For example the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band. The length of the overlap may be adjusted, for example, by means of a tangential screw mechanism to adjust the circumference of the band and thereby the amount by which the sclera is expanded [column 7, lines 1 through 12].

Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). It is not necessary that the reference teach what the subject application teaches, but only that the claim read on something disclosed in the reference, i.e., that all of the limitations in the claim be found in or fully met by the reference. Kalman v. Kimberly Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

In the examiner's view, Schachar's unillustrated scleral expansion band formed from a strip of material having adjustable overlapping ends responds to all of the limitations in claim 1.

The appellant counters that anticipation does not lie because this unillustrated embodiment lacks a first end and a second end as recited in the claim. In this regard, the appellant submits (1) that the claim, properly construed, requires the first and second ends to be free and/or unattached, and (2) that the overlapping ends of the Schachar band effectively cease to exist when the band is formed because they are attached and fastened together.

It is well settled that during patent examination claims are to be given their broadest reasonable interpretation consistent with the underlying specification without reading limitations from the specification into the claims. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). In the present case, the recitation in claim 1 that the prosthesis body has a first end and a second end is extremely broad. The claim neither requires the first and second ends to be free and/or unattached nor excludes these ends from being fastened or attached. The appellant's argument to the contrary rests on an improper attempt to read limitations from the specification into the claim.

Thus, the appellant's position that the subject matter recited in claim 1 distinguishes over that disclosed by Schachar is not persuasive. We shall therefore sustain the standing 35

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U.S.C. § 102(b) rejection of claim 1 as being anticipated by Schachar.

We also shall sustain the standing 35 U.S.C. § 102(b) rejection of claims 2 through 7 and 12 through 17 as being anticipated by Schachar. As the appellant has not argued separately the patentability of claims 1 through 7 and 12 through 17 apart from one another, claims 2 through 7 and 12 through 17 stand or fall with representative claim 1 (In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); In re Wood, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978)).

III. The 35 U.S.C. § 103(a) rejection of claims 8 through 11 and 18 through 21 as being unpatentable over Schachar

Claims 8 through 11 and 18 through 21 variously recite that at least one of the first and second prosthesis body ends has a top or bottom surface which is partially concave or convex. Implicitly conceding that Schachar does not disclose these features, the examiner nonetheless concludes that the provision of same to Schachar's adjustable scleral expansion band would have been obvious to suitably accommodate the overlapping ends.

Rejections based on 35 U.S.C. § 103(a) must rest on a factual basis. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967). In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may

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Application No. 09/589, 626

not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *Id.* In short, the examiner has advanced speculation and unfounded assumptions, rather than the requisite evidentiary basis, to support a conclusion that the admitted differences between the subject matter recited in claims 8 through 11 and 18 through 21 and Schachar are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Hence, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claims 8 through 11 and 18 through 21 as being unpatentable over Schachar.

SUMMARY

The decision of the examiner:

- a) to reject claims 1 through 21 under 35 U.S.C. § 101 is reversed;
- b) to reject claims 1 through 7 and 12 through 17 under 35 U.S.C. § 102(b) is affirmed; and
- c) to reject claims 8 through 11 and 18 through 21 under 35 U.S.C. § 103(a) is reversed.

Appeal No. 2005-0076
Application No. 09/589,626

AFFIRMED-IN-PART

[Signature]
IRWIN CHARLES COHEN)
Administrative Patent Judge)
)
) BOARD OF PATENT
[Signature]
CHARLES E. FRANKFORT)
Administrative Patent Judge)
) APPEALS AND
)
) INTERFERENCES
[Signature]
JOHN P. MCQUADE)
Administrative Patent Judge)

JPM/kis

Appeal No. 2005-0076
Application No. 09/589, 626

NOVAKOV, DAVIS & MUNCK, P.C.
900 THREE GALLERIA TOWER
13155 NOEL ROAD
DALLAS, TX 75240

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

DOCKETED

MAR 30 2005

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONALD A. SCHACHAR

~~RECEIVED~~ MAR 28 2005

MAR 28 2005

Appeal No. 2005-0076
Application No. 09/589, 626

DAVIS MUNCK

ON BRIEF

MAILED

MAR 24 2005

U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before COHEN, FRANKFORT, and MCQUADE, Administrative Patent Judges.

MCQUADE, Administrative Patent Judge.

ON REQUEST FOR REHEARING

Pursuant to 37 CFR § 41.52, Ronald A. Schachar requests rehearing (i.e., reconsideration) of our decision on appeal rendered November 23, 2004, and more specifically of that portion of the decision affirming the examiner's 35 U.S.C. § 102(b) rejection of claims 1 through 7 and 12 through 17 as being anticipated by U.S. Patent No. 5,354,331 to Schachar.¹

¹ In the decision, we also reversed the examiner's 35 U.S.C. § 101 rejection of claims 1 through 21 and 35 U.S.C. § 103(a) rejection of claims 8 through 11 and 18 through 21.

Consistent with our holding that claims 2 through 7 and 12 through 17 stand or fall with claim 1 for purposes of the appeal (see page 6 in the decision), the appellant's request focuses on claim 1.

In essence, the request rehashes the arguments advanced in the main and reply briefs. Such arguments are no more convincing now than they were before.

The appellant again contends that the Schachar reference is not anticipatory with respect to the subject matter recited in claim 1 because it does not meet the limitation in the claim requiring the recited prosthesis to comprise "a body having a first end and a second end." The relevant portion of the Schachar disclosure (see column 7, lines 1 through 12) describes a prosthesis in the form of a scleral expansion band comprising a strip of metal or synthetic resin having overlapping ends that are slid able past one another by means of a tangential screw mechanism to adjust the circumference of the band and thus the amount by which the sclera is expanded. The appellant submits that this band constitutes a closed circular ring which does not have first and second ends because the overlapping ends of the strip cease to exist after the scleral expansion band is formed.

According to the appellant, claim 1 is "directed to a scleral prosthesis that is not in the form of a closed circular ring" (request, page 3) and would be met by Schachar only if the band disclosed therein were modified or adjusted by being broken up into separate segments. The appellant urges that Schachar does not teach, suggest or provide an enabling disclosure for such a modification.

These arguments fail due to the broad scope of claim 1. As pointed out in the decision,

the recitation in claim 1 that the prosthesis body has a first end and a second end is extremely broad. The claim neither requires the first and second ends to be free and/or unattached nor excludes these ends from being fastened or attached. The appellant's argument to the contrary rests on an improper attempt to read limitations from the specification into the claim [page 5].

Claim 1 also does not exclude the prosthesis recited therein from being in the form of a closed circular ring. The subject limitation in the claim simply calls for the recited prosthesis to comprise "a body having a first end and a second end." Schachar's adjustable prosthesis clearly comprises such a body in the form of the strip of material having first and second ends. These ends do not cease to exist even when the strip assumes its operative configuration. Hence, the Schachar scleral expansion

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band, without any modification or adjustment thereto, fully meets the terms of the claim including the recitation of a body having a first end and a second end.

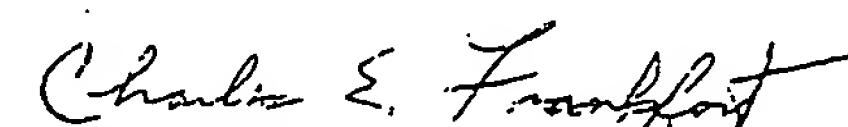
For these reasons, the arguments advanced in the appellant's request for rehearing are not persuasive of any error in our decision.

SUMMARY

In summary, we have reconsidered our decision to the extent requested by the appellant, but decline to make any changes therein.

DENIED


IRWIN CHARLES COHEN)
Administrative Patent Judge)


CHARLES E. FRANKFORT) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND INTERFERENCES


JOHN P. MCQUADE)
Administrative Patent Judge)

JPM/kis

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Application No. 09/589,626

NOVAKOV, DAVIS & MUNCK, P.C.
900 THREE GALLERIA TOWER
13155 NOEL ROAD
DALLAS, TX 75240

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing BRIEF OF APPELLANT SCHACHAR is being served on the following parties by the methods indicated on September 6, 2005:

Party Served

Ms. Linda Isacson, Esq.

Mr. Rob McManus, Esq.

Office of the Solicitor

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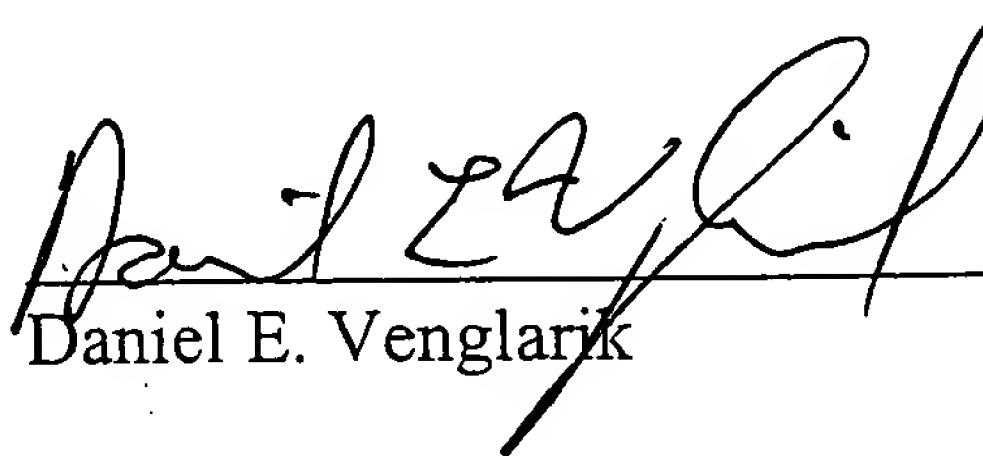
Alexandria, VA 22314

Method(s) of Service

Federal Express

9-6-05

Date



Daniel E. Venglarik